Statement on the monitoring of SARS-CoV-2 variants

Recently,the SARS-CoV-2 has discovered the newest SARS-CoV-2 variant "Omicron", whose Pango lineage is B.1.1.529.The Sejoy urgently established a special verification team to monitor and analyze the genetic data of the newly discovered SARS-CoV-2 variant; The Peptide probe sequence comparison results of the marketed products confirmed that the SARS-CoV-2 Antigen Rapid Test Cassette (Ref.:COVG-602ST) that has been marketed by Hangzhou Sejoy Electronics & Instruments Co.,Ltd. has no missed detection against the above-mentioned variant and still ensure the accuracy and sensitivity of the detection reagents.

Up to now, our company has monitored and analyzed the genetic data of major epidemic SARS-CoV-2 variants, including Alpha variant (B.1.1.7), Beta variant (B.1.351),Gamma variant(P.1) and Delta variant(B.1.617.2), Omicron variant (B1.1.529),our company will continue to pay attention to the variant of the SARS-CoV-2 to ensure that our company's SARS-CoV-2 Antigen Rapid Test Cassette (Ref.:COVG-602ST) will not miss detection and ensure the sensitivity, accuracy and specificity are not affected.

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

Hangzhou Sejoy Electronics & Instruments Co.,Ltd.

2021-11-30

EN ISO 13485: 2016 CERTIFICATION

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 095295 0001 Rev. 00

Holder of Certificate: **Hangzhou Sejoy Electronics & Instruments Co., Ltd.**
Area C, Building 2, No. 365, Wuzhou Road
Yuhang Economic Development Zone
311100 Hangzhou City, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Medical Device based on Immunochromatography, Dry Chemistry and Electrochemistry Method, Include Instrument, Test Strip and Control Solution**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 095295 0001 Rev. 00

Report No.: SH20167601

Valid from: 2020-10-30
Valid until: 2023-10-29

Date, 2020-10-30

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 095295 0001 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EC CERTIFICATE (SELF-TEST)

NO. 1434-IVDD-474/2021

CERTIFICATE

EC Certificate No. 1434-IVDD-474/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Hangzhou Sejoy Electronics & Instruments Co., Ltd
Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test Cassette
COVG-602ST

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 22.10.2021 to 27.05.2024

The date of issue of the Certificate: 22.10.2021

The date of the first issue of the Certificate: 22.10.2021

CE 1434

Issued under the Contract No. MD-100/2021
Application No: 192/2021
Certificate bears the qualified signature.
Warsaw, 22/10/2021
Module A1
FBM-30-E_10

Vice-President

EU DECLARATION OF CONFORMITY

(SARS-CoV-2 Antigen Rapid Test Cassette)

EU DECLARATION OF CONFORMITY

Manufacturer:	Hangzhou Sejoy Electronics& Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,YuhangEconomic Development Zone,Hangzhou City 311100 Zhejiang China
European Authorized Representative:	Shanghai International Holding Corp.GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	SARS-CoV-2 Antigen Rapid Test Cassette
Specification:	1 test/box， 5tests/box， 25tests/box
Classification:	Other device not listed under Annex II and self-testing of Directive 98/79/EC
Conformity assessment route:	Annex III,except Point 6,of Directive 98/79/EC
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 23640:2015, EN ISO 13612:2002, EN ISO 17511:2003, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13641:2002

CE

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Hangzhou, March 22, 2021
Place,date

General Manager
Legally binding signature, Position

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

EU DECLARATION OF CONFORMITY

(SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette)

EU DECLARATION OF CONFORMITY

Manufacturer:	Hangzhou Sejoy Electronics& Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,Hangzhou City 311100 Zhejiang China
European Authorized Representative:	Shanghai International Holding Corp.GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
Specification:	COVB-602
Classification:	Other device not listed under Annex II and self-testing of Directive 98/79/EC
Conformity assessment route:	Annex III,except Point 6,of Directive 98/79/EC
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 23640:2015, EN ISO 13612:2002, EN ISO 17511:2003, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13641:2002

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

Hangzhou, April 07, 2021
Place,date

General Manager
Legally binding signature, Position

EU DECLARATION OF CONFORMITY

(SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette)

EU DECLARATION OF CONFORMITY

Manufacturer:	Hangzhou Sejoy Electronics& Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,Hangzhou City 311100 Zhejiang China
European Authorized Representative:	Shanghai International Holding Corp.GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette
Specification:	COIF-522
Classification:	Other device not listed under Annex II and self-testing of Directive 98/79/EC
Conformity assessment route:	Annex III,except Point 6,of Directive 98/79/EC
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 23640:2015, EN ISO 13612:2002, EN ISO 17511:2003, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13641:2002

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

Hangzhou, April 09, 2021
Place,date

General Manager
Legally binding signature, Position

CONFIRMATION OF EU PRODUCT NOTIFICATIONS

FROM AUTHORIZED REPRESENTATIVE

Shanghai International Holding Corporation GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany

Confirmation

of EU product notifications

Herewith we confirm that

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraase 80, 20537 Hamburg, Germany

has taken over the function of an European Authorised Representative according to the requirements of IVD Directive 98/79/EC for:

Hangzhou Sejoy Electronics& Instruments Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone
311100 Hangzhou City, Zhejiang, China

for their in-vitro diagnostic device:
SARS-CoV-2 Antigen Rapid Test Cassette

and has submitted the product notifications at the relevant German Competent Authority according to Article 10(3) of the above mentioned IVD Directive and all supporting technical documents showing the devices' conformity with the Directive are deposited in our office.

15,04,2021

Mr. Liang Jin
-- on behalf of --
Shanghai International Holding
Corp. GmbH (Europe)

Tel.:(49) 40 2513175
Mail:
shholding@hotmail.com

Amtsgericht Hamburg
HRB 56 583
Geschäftsführer:
Liang Jin

Finanzamt Hamburg
Steuer-Nr.22/795/00590
Ust-ID-Nr.DE166892350

REGISTRATION CERTIFICATE FROM DIMDIV

(SARS-CoV-2 Antigen Rapid Test Cassette)

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00161905

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA05**		
	Bezeichnung / Name **Behörde für Justiz und Verbraucherschutz, Referat V43**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20310**
	Straße, Haus-Nr. / Street, house no. **Postfach 30 28 22**		
	Telefon / Phone **+49-40-428280**		Telefax / Fax **+49-40-427310017**
	E-Mail / E-mail **medizinprodukte@justiz.hamburg.de**		

Anzeige / Notification

	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **06.04.2021**		Registriernummer / Registration number **DE/CA05/IvD-238321-1708-01**
	Rechtsgrundlage / Legacy basis ☒ Medizinprodukte (98/79/EG) / German Medical Device Act (98/79/EG) ☐ Verordnung (EU) 2017/746 (IVDR) / Regulation (EU) 2017/746 (IVDR)		
	Typ der Anzeige / Notification type ☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn **DE/CA05/IvD-238321-1708-00**		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)

	Code **DE/0000040627**		
	Bezeichnung / Name **Shanghai International Holding Corporation GmbH (Europe)**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestrasse 80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hangzhou Sejoy Electronics& Instruments Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Hangzhou City, Zhejiang**		Postleitzahl / Postal code **311100**
	Straße, Haus-Nr. / Street, house no. **Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone**		
	Telefon / Phone **+86-571-81957767**		Telefax / Fax **+86-571-81957750**
	E-Mail / E-mail **zhangyy@sejoy.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG			
	Bezeichnung / Name **Liang Jin**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestr.80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device

Klassifizierung / Classification

☐ Produkt der Liste A, Anhang II / Device of List A, Annex II

☐ Produkt der Liste B, Anhang II / Device of List B, Annex II

☐ Produkt zur Eigenanwendung / Device for self-testing

☒ Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)

App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no

Anzeige nach § 25 Abs. 3 Nummer 3 MPG

Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG

☐ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"

Handelsname des Produktes / Trade name of the device

Sejoy

Produktbezeichnung / Name of device

SARS-CoV-2 Antigen Rapid Test Cassette

Angabe der benutzten Nomenklatur / Nomenclature used

☒ EDMS-Klassifikation / EDMS Classification

☐ GMDN

Nomenklaturcode / Nomenclature code

15-70-90-90-00

Nomenklaturbezeichnung / Nomenclature term

OTHER OTHER VIROLOGY RAPID TESTS

Kurzbeschreibung / Short description

In Deutsch / In German

In Englisch / In English

The SARS-CoV-2 Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigen in human Oropharyngeal swabs, Nasal swabs, Nasopharyngeal swabs, Saliva. The identification is based on the monoclonal antibodies specific for the Nucleocapsid (N) Protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of COVID-19 infection.

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices

Nummer(n) der Bescheinigung(en) / Certificate number(s)

☐ In übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A)

In conformity with Common Technical Specifications (for Annex II List A devices)

Ergebnisse der Leistungsbewertung

Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort City	**Hamburg**	Datum Date	**2021-03-16**
		Name	**Liang Jin**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Sylvia Frenzel**		Telefon / Phone **040 42837-2120**

REGISTRATION CERTIFICATE FROM DIMDIV

(SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette)

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00162615

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA05**		
	Bezeichnung / Name **Behörde für Justiz und Verbraucherschutz, Referat V43**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20310**
	Straße, Haus-Nr. / Street, house no. **Postfach 30 28 22**		
	Telefon / Phone **+49-40-428280**		Telefax / Fax **+49-40-427310017**
	E-Mail / E-mail **medizinprodukte@justiz.hamburg.de**		

Anzeige / Notification

	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **28.04.2021**		Registriernummer / Registration number **DE/CA05/IvD-238321-1776-00**
	Rechtsgrundlage / Legacy basis ☒ Medizinprodukte (98/79/EG) / German Medical Device Act (98/79/EG) ☐ Verordnung (EU) 2017/746 (IVDR) / Regulation (EU) 2017/746 (IVDR)		
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)

	Code **DE/0000040627**		
	Bezeichnung / Name **Shanghai International Holding Corporation GmbH (Europe)**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestrasse 80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax
	E-Mail / E-mail **shholding@hotmail.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hangzhou Sejoy Electronics& Instruments Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Hangzhou City, Zhejiang**		Postleitzahl / Postal code **311100**
	Straße, Haus-Nr. / Street, house no. **Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone**		
	Telefon / Phone **+86-571-81957767**		Telefax / Fax
	E-Mail / E-mail **zhangyy@sejoy.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Liang Jin**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestr.80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax
	E-Mail / E-mail **shholding@hotmail.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device

Klassifizierung / Classification
☐ Produkt der Liste A, Anhang II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung / Device for self-testing
☒ Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)

App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no

Anzeige nach § 25 Abs. 3 Nummer 3 MPG
Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG
☐ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"

Handelsname des Produktes / Trade name of the device
Sejoy

Produktbezeichnung / Name of device
SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette

Angabe der benutzten Nomenklatur / Nomenclature used
☒ EDMS-Klassifikation / EDMS Classification
☐ GMDN

Nomenklaturcode / Nomenclature code
15-04-80-90-00

Nomenklaturbezeichnung / Nomenclature term
OTHER VIRAL ANTIGEN/ANTIBODY DETECTION

Kurzbeschreibung / Short description
In Deutsch / In German

In Englisch / In English
SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2, influenza A and influenza B viral nucleoprotein antigens in nasopharyngeal swab / oropharyngeal swab from individuals suspected of respiratory viral infection consistent with SARS-CoV-2 by their healthcare provider. Symptoms of Respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices

Nummer(n) der Bescheinigung(en) / Certificate number(s)

☐ In übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A)
In conformity with Common Technical Specifications (for Annex II List A devices)

Ergebnisse der Leistungsbewertung
Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort City	**Hamburg**	Datum Date	**2021-04-15**
		Name	**Liang Jin**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Sylvia Frenzel**		Telefon / Phone **040 42837-2120**

CHINESE WHITELIST OF SEJOY FOR EXPORT

取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

杭州世佳电子有限公司 检索

企业名称（中文）	企业名称（英文）	产品类别	产品名称/型号	统一社会信用代码	国外注册认证情况
杭州世佳电子有限公司	Hangzhou Sejoy Electronics &. Instruments Co.,Ltd	红外体温计	Infrared Ear/Forehead Thermometer (ET-306,ET-215,ET-206,ET-305)	91330160742011788U	欧盟CE
杭州世佳电子有限公司	Hangzhou Sejoy Electronics &. Instruments Co.,Ltd	新型冠状病毒检测试剂	COVID-19 IgG/IgM Rapid Test Cassette SARS-CoV-2 Antigen Rapid Test Cassette	91330160742011788U	欧盟CE

CERTIFICATE OF FREE SALE (Philippines)

中国医药保健品进出口商会
China Chamber of Commerce for Import & Export of Medicines & Health Products
Add:11-12/F, Bldg3, Beijing INN, No.8 Beisihuan Hutong, Dongcheng Dist, Beijing, China P.C.100010
Tel: 0086-10-58036372/75/78/71/70 Fax: 0086-10-58036274 Website: www.cccmhpie.org.cn
E-mail: 110982716@qq.com 825795117@qq.com mail@cccmhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB0584

产品名称：新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）、
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）
Product(s): SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 IgG/IgM Rapid Test Cassette

规格型号：COVG-602，COV-402
Model: COVG-602, COV-402

销往国家：菲律宾
Export to: Philippines

出口商：杭州世佳电子有限公司
Exporter: Hangzhou Sejoy Electronics & Instruments Co.,LTD.

出口商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address:Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

制造商：杭州世佳电子有限公司
MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.

制造商地址:杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
ADDRESS:Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

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此证明自签发时起有效期 2 年。
THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 3 月 22 日
DATE OF ISSUE:March 22, 2021

CERTIFICATE OF FREE SALE (Thailand)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add: 11-12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Qiit, Beijing, China P.C. 100010

Tel: 0086 10 58036272/75/78/71/70 Fax: 0086 10 58036274 Website: www.cccmhpie.org.cn

E-mail: 1109827394@qq.com 82579517@qq.com mail@cccmhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB041RD

产品名称：	新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法） 新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法） 新型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法） 新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）
Product(s):	SARS-CoV-2 Antigen Rapid Test Cassette COVID-19 IgG/IgM Rapid Test Cassette SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette
规格型号： Model：	COVG-602、COV-402、COVB-602、COIF-522 COVG-602, COV-402, COVB-602, COIF-522
销往国家： Export to:	泰国 Thailand
出口商： Exporter:	杭州世佳电子有限公司 Hangzhou Sejoy Electronics & Instruments Co., LTD.
出口商地址： Address:	杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区 Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China
制造商: Manufacturer:	杭州世佳电子有限公司 Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
制造商地址： Address:	杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区 Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone,311100 Hangzhou City, Zhejiang, China

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此证明自签发时起有效期 2 年。
THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 8 月 3 日
DATE OF ISSUE: Aug 3, 2021

CERTIFICATE OF FREE SALE (Vietnam)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:11-12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Dist, Beijing, China P.C:100010

Tel: 0086-10-58036272/35/78/71/70 Fax: 0086-10-58036274 Website: www.cccmhpie.org.cn

E-mail: 110982739@qq.com 82579517@qq.com mail@cccmhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB029RD

产品名称： 新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）
新型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法）
新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）

Product(s): SARS-CoV-2 Antigen Rapid Test Cassette
COVID-19 IgG/IgM Rapid Test Cassette
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette

规格型号： COVG-602、COV-402、COVB-602、COIF-522
Model: COVG-602, COV-402, COVB-602, COIF-522

销往国家： 越南
Export to: Vietnam

出口商： 杭州世佳电子有限公司
Exporter: Hangzhou Sejoy Electronics & Instruments Co., LTD.

出口商地址： 杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address: Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

制造商: 杭州世佳电子有限公司
Manufacturer: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.

制造商地址： 杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address: Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone,311100 Hangzhou City, Zhejiang, China

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THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 7 月 27 日
DATE OF ISSUE: July 27, 2021

CERTIFICATE OF FREE SALE (Indonesia)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:11-12/F, Bldg.3, Beijing 3NN, No.6 Neizhagan Hutong, Dongcheng Dist, Beijing, China P.C:100010

Tel: 0086-10-58056272/75/78/71/70 Fax: 0086-10-58056274 Website: www.cccmhpie.org.cn

E-mail: 1109432739@qq.com 825795172@qq.com mds@cccmhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB1811

产品名称：新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）
型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法）
新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）

Product(s):SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 IgG/IgM Rapid Test Cassette
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette

规格型号：COVG-602、COV-402、COVB-602、COIF-522、COVG-602ST
Model: COVG-602, COV-402, COVB-602, COIF-522, COVG-602ST

销往国家：印度尼西亚
Export to: Indonesia

出口商： 杭州世佳电子有限公司
Exporter: Hangzhou Sejoy Electronics & Instruments Co.,LTD.

出口商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address:Area C, Building 2,No.365,Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

制造商： 杭州世佳电子有限公司
MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.

制造商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
ADDRESS:Area C, Building 2,No.365,Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

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THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 8 月 23 日
DATE OF ISSUE:August 23, 2021

CERTIFICATE OF FREE SALE (Cambodia)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:11~12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Dist, Beijing, China P.C.100010

Tel: 0086 10 58036272/71/78/73/70 Fax: 0086 10 58036274 Website: www.ccemhpie.org.cn

E-mail: 310982739@qq.com 825795177@qq.com md@ccemhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB0949

产品名称： 新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）、
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）
型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法）
新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）

Product(s): SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 IgG/IgM Rapid Test Cassette
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette

规格型号： COVG-602、COV-402、COVB-602、COIF-522
Model: COVG-602, COV-402, COVB-602, COIF-522

销往国家： 柬埔寨
Export to: Cambodia

出口商： 杭州世佳电子有限公司
Exporter: Hangzhou Sejoy Electronics & Instruments Co.,LTD.

出口商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address: Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

制造商： 杭州世佳电子有限公司
MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.

制造商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
ADDRESS:Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

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THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 5 月 12 日
DATE OF ISSUE:May 12, 2021

CERTIFICATE OF FREE SALE (Bangladesh)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:11-12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Dist, Beijing, China P.C.100010

Tel: 0086-10-58036272/75/78/71/70 Fax: 0086-10-58036274 Website: www.cccmhpie.org.cn

E-mail: 1109827796@qq.com 825195176qq.com md@cccmhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB1939

产品名称： 新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）
新型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法）
新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）
新型冠状病毒（2019-nCOV）口含式抗原检测试剂盒（胶体金法）

Product(s):SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 IgG/IgM Rapid Test Cassette
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette
SARS-CoV-2 Antigen Saliva Lolly Test

规格型号：COVG-602、COVG-602ST、COV-402、COVB-602、COIF-522、COVG-603
Model： COVG-602、COVG-602ST、COV-402、COVB-602、COIF-522、COVG-603

销往国家：孟加拉
Export to：Bangladesh

出口商： 杭州世佳电子有限公司
Exporter： Hangzhou Sejoy Electronics & Instruments Co.,LTD.
出口商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address: Area C,Building 2,No.365,Wuzhou Road,Yuhang Economic Development Zone, 311100 Hangzhou City,Zhejiang, China

制造商： 杭州世佳电子有限公司
MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
制造商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
ADDRESS: Area C,Building 2,No.365,Wuzhou Road,Yuhang Economic Development Zone, 311100 Hangzhou City,Zhejiang, China

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THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 9 月 9 日
DATE OF ISSUE:September 9, 2021

CERTIFICATE OF FREE SALE (Pakistan)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:13-12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Qu, Beijing, China P.C.100010

Tel: 0086-10-58036272/75/78/71/70 Fax: 0086-10-58036274 Website: www.ccemhpie.org.cn

E-mail: 330982739@qq.com 82579517@qq.com mb@ccemhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB2240

产品名称：新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）
型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法）
新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）
新型冠状病毒（2019-nCOV）抗原口含检测试剂盒（胶体金法）

Product(s): SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 IgG/IgM Rapid Test Cassette
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette
SARS-CoV-2 Antigen Saliva Lolly Test

规格型号： COVG-602、COV-402、COVB-602、COIF-522、COVG-602ST、COVG-603
Model： COVG-602、COV-402、COVB-602、COIF-522、COVG-602ST、COVG-603

销往国家： 巴基斯坦
Export to: Pakistan

出口商： 杭州世佳电子有限公司
Exporter: Hangzhou Sejoy Electronics & Instruments Co.,LTD.
出口商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address:Area C,Building 2,No.365,Wuzhou Road,Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

制造商： 杭州世佳电子有限公司
MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
制造商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
ADDRESS:Area C,Building 2,No.365,Wuzhou Road,Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

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此证明自签发时起有效期 2 年。
THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 11 月 4 日
DATE OF ISSUE:November 4, 2021

CERTIFICATE OF FREE SALE (Tunisia)

中国医药保健品进出口商会
China Chamber of Commerce for Import & Export of Medicines & Health Products
Add:11-12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Qist, Beijing, China P.C.100010
Tel: 0086 10 58036272/75/78/71/70 Fax: 0086 10 58036274 Website: www.cccmhpie.org.cn
E-mail: 110982739@qq.com 82379517@qq.com net@cccmhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB1532

产品名称：新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）
型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法）
新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）

Product(s):SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 lgG/lgM Rapid Test Cassette
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette

规格型号：COVG-602、COV-402、COVB-602、COIF-522
Model: COVG-602, COV-402, COVB-602, COIF-522

销往国家： 突尼斯
Export to: Tunisia

出口商： 杭州世佳电子有限公司
Exporter: Hangzhou Sejoy Electronics & Instruments Co.,LTD.
出口商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address:Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

制造商： 杭州世佳电子有限公司
MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
制造商地址:杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
ADDRESS:Area C, Building 2, No.365,Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

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此证明自签发时起有效期 2 年。
THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 7 月 21 日
DATE OF ISSUE:July 21, 2021

CERTIFICATE OF FREE SALE (South Africa)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:(1-12/F, Bldg3, Beijing INN, No.6 Nanshagan Hutong, Dongcheng Dist, Beijing, China P.C.100013
Tel: 0086-10-58036272/75/78/71/70 Fax: 0086-10-58036274 Website: www.cccmhpie.org.cn
E-mail: 109827759@qq.com 825795178@qq.com md@cccmhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB0583

产品名称：新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）、
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）

Product(s):SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 IgG/IgM Rapid Test Cassette

规格型号：COVG-602，COV-402
Model: COVG-602, COV-402

销往国家：南非
Export to: South Africa

出口商：杭州世佳电子有限公司
Exporter: Hangzhou Sejoy Electronics & Instruments Co.,LTD.

出口商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address:Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

制造商：杭州世佳电子有限公司
MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.

制造商地址:杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
ADDRESS:Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

兹证明上述产品符合相关标准，未在中国注册，该产品出口不受限制
THIS IS TO CERTIFY THAT THE ABOVE PRODUCT COMPLIES WITH THE RELEVANT STANDARDS, HAVE NOT BEEN REGISTERED IN CHINA. THE EXPORTATION OF THE PRODUCT IS NOT RESTRICTED.

此证明自签发时起有效期 2 年。
THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 3 月 22 日
DATE OF ISSUE:March 22, 2021

CERTIFICATE OF FREE SALE (Colombia)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

A06(11-12/)Bldg3, Beijing INN, No.8 Nanzhugan Hutong, Dongcheng Dist, Beijing, China P.C.100010

Tel: 0086 10 58036272/75/78/71/70 Fax: 0086 10 58036274 Website: www.cccmhpie.org.cn

E-mail: 1109827190@qq.com 82579517@qq.com md@cccmhpie.org.cn

自 由 销 售 证 书

CERTIFICATE OF FREE SALE

2021YB028RD

产品名称:	新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法） 新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法） 新型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法） 新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）
Product(s):	SARS-CoV-2 Antigen Rapid Test Cassette COVID-19 IgG/IgM Rapid Test Cassette SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette
规格型号: Model:	COVG-602、COV-402、COVB-602、COIF-522、COVG-602ST COVG-602, COV-402, COVB-602, COIF-522, COVG-602ST
销往国家: Export to:	哥伦比亚 Colombia
出口商: Exporter:	杭州世佳电子有限公司 Hangzhou Sejoy Electronics & Instruments Co., LTD.
出口商地址: Address:	杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区 Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China
制造商: Manufacturer:	杭州世佳电子有限公司 Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
制造商地址: Address:	杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区 Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone,311100 Hangzhou City, Zhejiang, China

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THIS IS TO CERTIFY THAT THE ABOVE PRODUCTS COMPLIE WITH THE RELEVANT STANDARDS, HAVE NOT BEEN REGISTERED IN CHINA. THE EXPORTATION OF THE PRODUCTS IS NOT RESTRICTED.

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中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 7 月 27 日
DATE OF ISSUE: July 27, 2021

CERTIFICATE OF FREE SALE (The Republic of Ecuador)

中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:11-12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Dist, Beijing, China P.C.100010

Tel: 0086 10 58036272/75/76/71/70 Fax: 0086 10 58036274 Website: www.cccmhpie.org.cn

E-mail: 116982739@qq.com 82579517@qq.com md@cccmhpie.org.cn

自 由 销 售 证 书

CERTIFICATE OF FREE SALE

2021YB1240

产品名称：新型冠状病毒（2019-nCOV）抗原检测试剂盒（胶体金法）、
新型冠状病毒（2019-nCOV）抗体检测试剂盒（胶体金法）
型冠状病毒（SARS-CoV-2） 中和抗体检测试剂盒（胶体金法）
新型冠状病毒&甲/乙型流感病毒联合检测试剂（胶体金法）
毒品多合一检测试剂盒

Product(s):SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 lgG/lgM Rapid Test Cassette
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette
Multi-drug Rapid Test (Urine)

规格型号： COVG-602、COV-402、COVB-602、COIF-522
Model: COVG-602, COV-402, COVB-602, COIF-522

销往国家： 厄瓜多尔
Export to: The Republic of Ecuador

出口商： 杭州世佳电子有限公司
Exporter: Hangzhou Sejoy Electronics & Instruments Co.,LTD.
出口商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
Address: Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

制造商： 杭州世佳电子有限公司
MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
制造商地址：杭州市余杭区余杭经济技术开发区五洲路 365 号 2 幢 C 区
ADDRESS: Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

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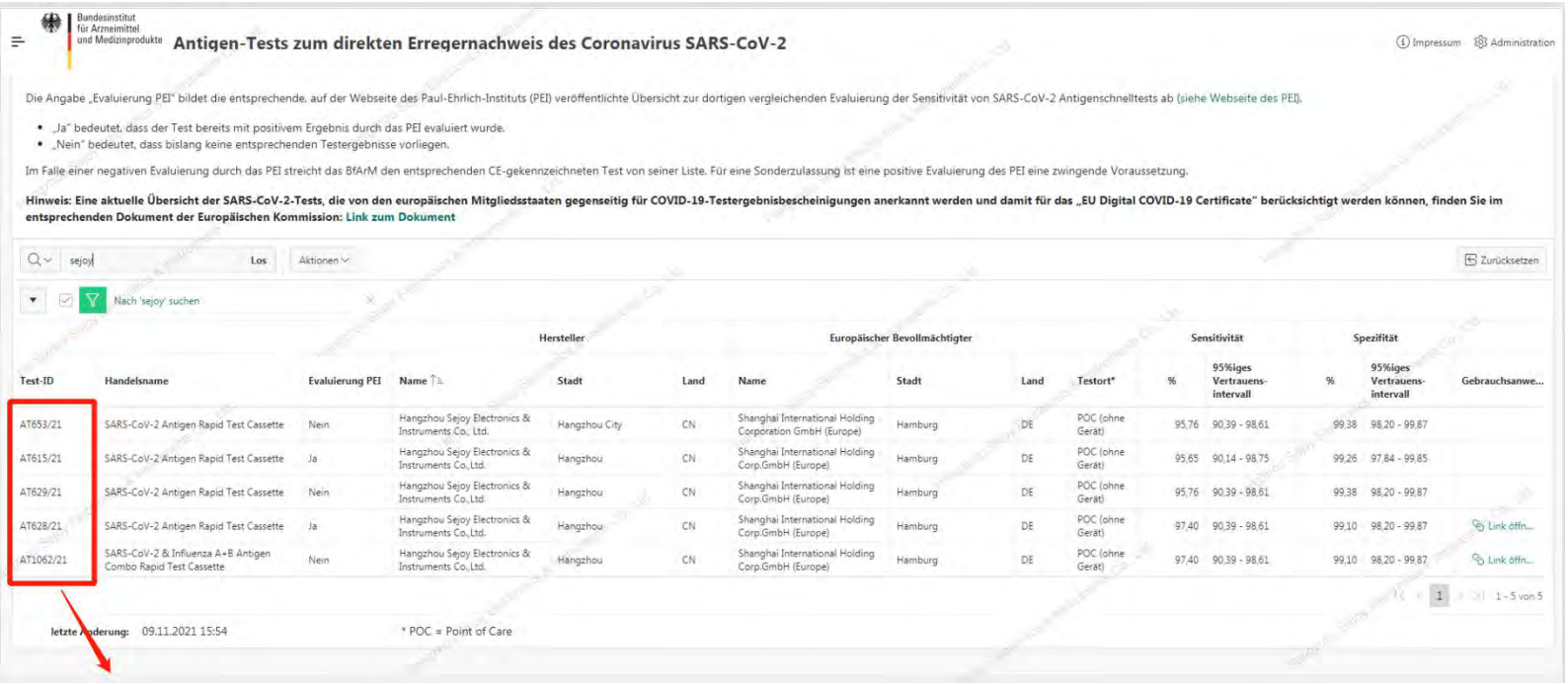
THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 6 月 16 日
DATE OF ISSUE:June 16, 2021

GERMAN PROFESSIONAL WHITELIST OF ANTIGEN-TESTS



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum Administration

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument

sejoy Los Aktionen Zurücksetzen

Nach 'sejoy' suchen

			Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test-ID	Handelsname	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall	Gebrauchsanwe...
AT653/21	SARS-CoV-2 Antigen Rapid Test Cassette	Nein	Hangzhou Sejoy Electronics & Instruments Co., Ltd.	Hangzhou City	CN	Shanghai International Holding Corporation GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	95,76	90,39 - 98,61	99,38	98,20 - 99,87	
AT615/21	SARS-CoV-2 Antigen Rapid Test Cassette	Ja	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Hangzhou	CN	Shanghai International Holding Corp.GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	95,65	90,14 - 98,75	99,26	97,84 - 99,85	
AT629/21	SARS-CoV-2 Antigen Rapid Test Cassette	Nein	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Hangzhou	CN	Shanghai International Holding Corp.GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	95,76	90,39 - 98,61	99,38	98,20 - 99,87	
AT628/21	SARS-CoV-2 Antigen Rapid Test Cassette	Ja	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Hangzhou	CN	Shanghai International Holding Corp.GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	97,40	90,39 - 98,61	99,10	98,20 - 99,87	Link öffn...
AT1062/21	SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette	Nein	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Hangzhou	CN	Shanghai International Holding Corp.GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	97,40	90,39 - 98,61	99,10	98,20 - 99,87	Link öffn...

1 - 5 von 5

letzte Änderung: 09.11.2021 15:54

* POC = Point of Care

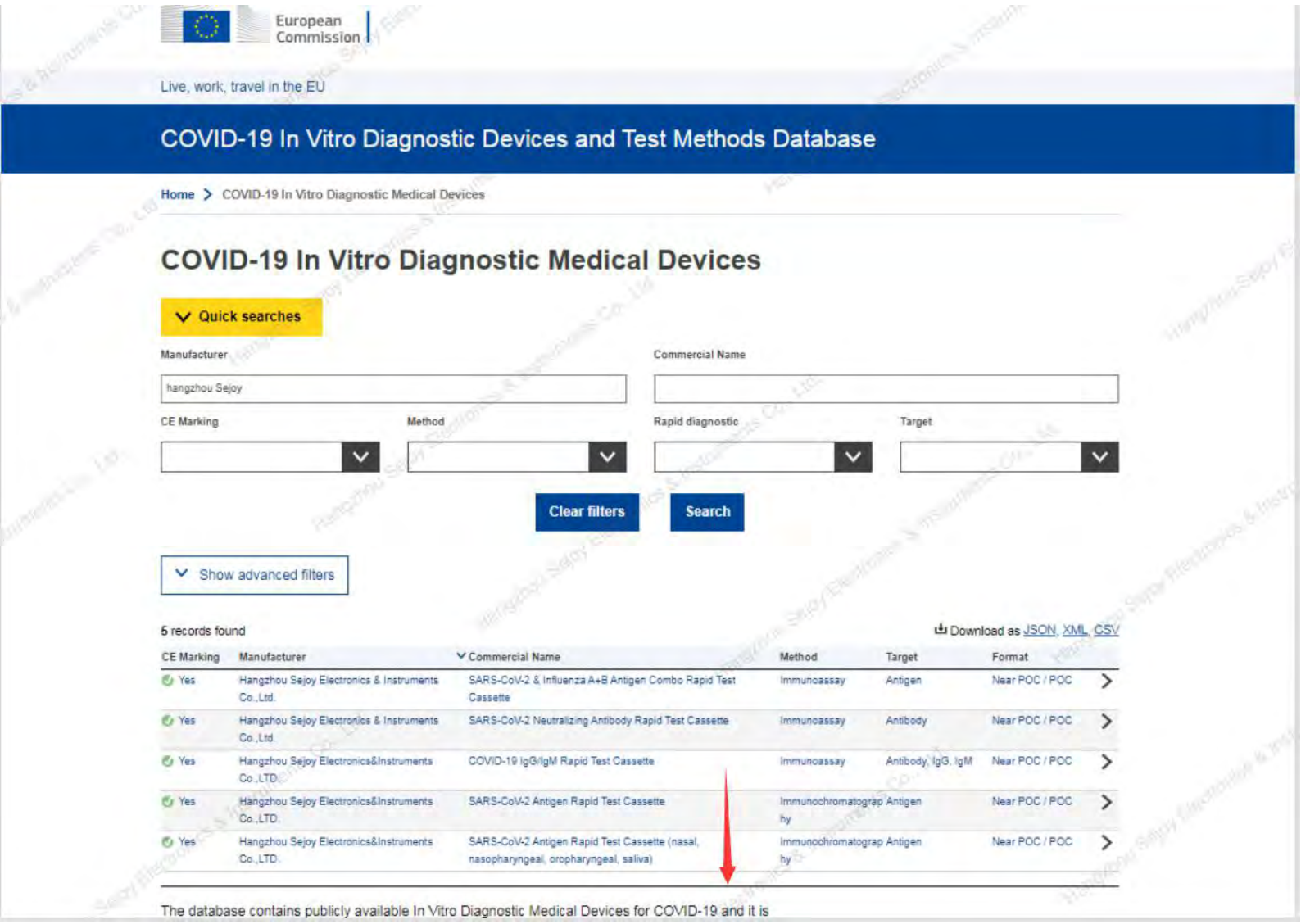
AT653/21——SARS-CoV-2 Antigen Rapid Test Cassette (Oropharyngeal)

AT615/21——SARS-CoV-2 Antigen Rapid Test Cassette (Saliva)

AT629/21——SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal)

AT628/21——SARS-CoV-2 Antigen Rapid Test Cassette (Nasal)

EU JRC WHITELIST



European Commission

Live, work, travel in the EU

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

Home > COVID-19 In Vitro Diagnostic Medical Devices

COVID-19 In Vitro Diagnostic Medical Devices

Quick searches

Manufacturer: hangzhou Sejoy

Commercial Name

CE Marking | Method | Rapid diagnostic | Target

Clear filters | Search

Show advanced filters

5 records found

Download as JSON, XML, CSV

CE Marking	Manufacturer	Commercial Name	Method	Target	Format
Yes	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette	Immunoassay	Antigen	Near POC / POC
Yes	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette	Immunoassay	Antibody	Near POC / POC
Yes	Hangzhou Sejoy Electronics&Instruments Co.,LTD.	COVID-19 IgG/IgM Rapid Test Cassette	Immunoassay	Antibody, IgG, IgM	Near POC / POC
Yes	Hangzhou Sejoy Electronics&Instruments Co.,LTD.	SARS-CoV-2 Antigen Rapid Test Cassette	Immunochromatography	Antigen	Near POC / POC
Yes	Hangzhou Sejoy Electronics&Instruments Co.,LTD.	SARS-CoV-2 Antigen Rapid Test Cassette (nasal, nasopharyngeal, oropharyngeal, saliva)	Immunochromatography	Antigen	Near POC / POC

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is

5 records found

CE Marking	Manufacturer	Commercial Name
Yes	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette
Yes	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
Yes	Hangzhou Sejoy Electronics&Instruments Co.,LTD.	COVID-19 IgG/IgM Rapid Test Cassette
Yes	Hangzhou Sejoy Electronics&Instruments Co.,LTD.	SARS-CoV-2 Antigen Rapid Test Cassette
Yes	Hangzhou Sejoy Electronics&Instruments Co.,LTD.	SARS-CoV-2 Antigen Rapid Test Cassette (nasal, nasopharyngeal, oropharyngeal, saliva)

REGISTRATION CERTIFICATE OF BULGARIA

Уведомление за пуснати на пазара и/или в действие ин витро диагностични медицински изделия, на територията на РБългария, в съответствие с чл. 29, ал. 1 и 2 от ЗМИ/ IVD Directive чл.10.6

Form for the notification of In Vitro Diagnostic Medical Devices in accordance with art. 29 (1) and (2) of MDL/ IVDMD Directive, Art.10.6

1.	**А. Данни за компетентния орган / Identification of the Competent Authority** Код на компетентния орган / Competent Authority code * BG/CA01	ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА 1303 София, ул. „Д. Груев" №8 Регистрационен индекс и дата ИМ-16443/ 11.03.2020
	Име на компетентния орган / Competent Authority name *Изпълнителна агенция по лекарствата / Bulgarian Drug Agency*	
	Код на страната / Country code * BG	
	Град / City София	Пощенски код / Postal code 1303
	Улица, номер / Street, Number *Дамян Груев 8*	Пощенска кутия / PO box
	Телефон / Phone (+359 2) 890 35 11	Факс / Fax (+359 2) 890 34 34
	E-mail bda@bda.bg	
2.	**Б. Данни за регистрацията в ЕС или ЕИП / Identification of the registration in EU or EEA** Дата на регистрация / Registration date at Competent authority * 30.04.2020	Регистрационен номер / Registration number* DE/CA05/IvD-238321-1396-00
3.	**Означете, дали това е първо уведомяване, промяна на информацията, прекратяване или заличаване на регистрация / Indicate if this is a first notification, a change of information, a discontinuation or a withdrawal *** ☑ първа / first ☐ промяна на адреса / change of address ☐ значителна промяна в информацията за изделието / significant change of product information ☐ промяна в сертификата / changes of certificate ☐ отказ от компетентния орган / withdrawal by Competent Authority ☐ прекратяване от производителя. Изтегляне поради прекратяване на предлагането / discontinuation by manufacturer. Withdrawn because discontinuation of placing on the market	
4.	**Ако е промяна, оттегляне или прекратяване, посочете предишен регистрационен номер / If change, discontinuation or withdrawal provide previous registration number *** ☐	
5.	**Статут на организацията, която подава формата / Status of the organization making this notification:** ☐ Производител / Manufacturer * ☐ Упълномощен представител / Authorized representative * ☒ Лице, отговорно за пускане на пазара, търговец или вносител / The person who is responsible for placing on the market including distributor or importer	
6.	**Означете, дали това е промяна на адреса на производителя / Indicate if this is a change of Manufacture's address *** ☐ промяна на адреса / change of address	
7.	**С. Данни за производителя / Identification of the Manufacturer** Код на производителя / Manufacturer code * 9133010674201178 8U	
	Име на производителя, пълно / Manufacturer name, long **Hangzhou Sejoy Electronics & Instruments Co., Ltd. - China**	
	Име на производителя, кратко / Manufacturer name, short	

REGISTRATION CERTIFICATE OF CZECH

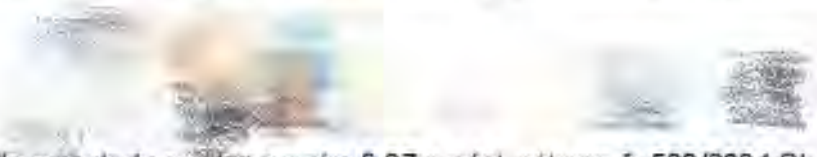
MINISTERSTVO ZDRAVOTNICTVÍ
Palackého náměstí 375/4, 12801 Praha 2

Praha 18. března 2021
Č. j.: MZDR 9907/2021-2/OLZP

MZDRX01F3AQF

ROZHODNUTÍ

Ministerstvo zdravotnictví (dále jen „Ministerstvo") jako orgán příslušný k rozhodnutí podle ustanovení § 12 odst. 1 písm. h) zákona č. 22/1997 Sb., o technických požadavcích na výrobky a o změně a doplnění některých zákonů, ve znění pozdějších předpisů ve spojení s § 4 odst. 8 nařízení vlády č. 56/2015 Sb., o technických požadavcích na diagnostické zdravotnické prostředky in vitro (dále jen „nařízení vlády"), na základě žádosti společnosti



rozhodlo v souladu s ustanovením § 67 a násl. zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů (dále jen „správní řád") tak, že

p o v o l u j e

žadateli uvést na trh a do provozu diagnostický zdravotnický prostředek in vitro **SARS-CoV-2 Antigen Rapid Test Cassette,** jehož výrobcem je Hangzhou Sejoy Electronics& Instruments Co.,Ltd. se sídlem Area C, Building 2, No.365, Wuzhou Road,YuhangEconomic Development Zone,Hangzhou City 311100 Zhejiang China, pro použití laickou osobou

a s t a n o v u j e

po dobu platnosti tohoto rozhodnutí žadateli následující povinnosti k zajištění ochrany veřejného zdraví:

- zajistit, aby konečný laický uživatel testu byl informován, že toto povolení se nevztahuje na variantu testu, která využívá nazofaryngeálního odběru vzorku
- informovat odběratele o povinnosti v rámci testování zajistit při pozitivitě antigenního testu provedeného laickou osobou bezprostřední informování poskytovatele zdravotních služeb za účelem provedení konfirmačního testu,
- v případě zájmu odběratele zajistit proškolení určené osoby,
- hlásit Státnímu ústavu pro kontrolu léčiv každou nepříznivou událost, ke které během používání výrobku dojde.

Platnost povolení: **do 30. 4. 2021**.

Odůvodnění:

I.

Dne 8. 3. 2021 požádal žadatel o udělení výjimky podle § 4 odst. 8 nařízení pro diagnostický zdravotnický prostředek in vitro určený k sebetestování na onemocnění COVID–19 pod obchodním názvem SARS-CoV-2 Antigen Rapid Test Cassette, výrobce Hangzhou Sejoy Electronics& Instruments Co.,Ltd., pro účely zavedení celoplošného testování v České republice, jakožto diagnostického zdravotnického prostředku in vitro, pro který nebyl proveden postup podle § 4 odst. 1 až 4 nařízení a jehož použití je v zájmu ochrany zdraví. Žádost zdůvodňuje potřebou pravidelně testovat populaci za účelem včasného odhalení výskytu nových případů onemocnění COVID-19 ještě před jejich rozšířením v kolektivu.

K žádosti přikládá následující dokumentaci:

a) Declaration of Conformity
b) Návod k použití v českém jazyce
c) Fotodokumentace
d) Clinical Report

II.

Ministerstvo posoudilo předmětný diagnostický zdravotnický prostředek in vitro na základě žadatelem předložených informací jako dostatečně funkčně způsobilý a pro uživatele bezpečný.

Ministerstvo se ztotožňuje s potřebou pravidelně testovat veřejnost rychlými antigenními testy za účelem včasného odhalení výskytu nových případů onemocnění COVID-19 ještě před jejich rozšířením v kolektivech, což při absenci antigenních testů určených pro sebetestování na celém trhu EU není možné řešit jinak, než s použitím vhodných antigenních testů určených pro profesionální použití, jež budou k tomuto účelu použity za účelem odhalení pozitivních osob ve společnosti. Povolení se vztahuje pouze na neinvazivní způsoby odběru vzorku.

Za účelem podpory opatření k ochraně veřejného zdraví je žadateli uložena povinnost informovat odběratele o povinnosti při zjištěné pozitivitě antigenního testu provedeného laickou osobou kontaktovat vzdáleným přístupem (telefonicky, e-mailem apod.) závodního lékaře (poskytovatele pracovně – lékařských služeb) nebo registrujícího praktického lékaře, který rozhodne o provedení konfirmačního testu a zajistí komunikaci v rámci systému ISIN. Za účelem minimalizace rizika chyb v provedení odběru a interpretaci výsledků testů je žadateli uložena povinnost v případě zájmu odběratele zajistit proškolení osoby určené odběratelem.

S ohledem na potřebu dalšího vyhodnocování z hlediska bezpečnosti a funkční způsobilosti testů je výjimka z procesu posouzení shody udělena do 30. 4. 2021.

S ohledem na výše uvedené rozhodlo Ministerstvo tak, jak je uvedeno ve výroku tohoto rozhodnutí.

Poučení:

Proti tomuto rozhodnutí je možné podat v souladu s § 152 odst. 1 správního řádu u Ministerstva rozklad, a to ve lhůtě 15 dnů ode dne doručení. O rozkladu rozhoduje ministr zdravotnictví.

doc. MUDr. Jan Blatný, Ph.D.
ministr zdravotnictví
podepsáno elektronicky

REGISTRATION CERTIFICATE OF LITHUANIA

(SARS-CoV-2 Antigen Rapid Test Cassette Self-Test Use)

VALSTYBINĖ AKREDITAVIMO SVEIKATOS PRIEŽIŪROS VEIKLAI TARNYBA PRIE SVEIKATOS APSAUGOS MINISTERIJOS

Biudžetinė įstaiga, buveinė A. Juozapavičiaus g. 9, LT-09311 Vilnius, tel. (8 5) 261 5177, faks. (8 5) 212 7310, el. paštas vaspvt@vaspvt.gov.lt, interneto svetainė www.vaspvt.gov.lt.
Duomenys kaupiami ir saugomi Juridinių asmenų registre, kodas 191352247

Sveikatos apsaugos ministerijai
ministerija@sam.lt

2021-05-19 Nr. D2-7302-(1.11)

Kopija:
UAB „Optifarma“
Gedvydžių g. 24-2
LT-06308, Vilnius
info@optifarma.lt

2021-04-22 Paraišką (D1-2712, D1-3022)

DĖL GREITŲJŲ ANTIGENO TESTŲ, SKIRTŲ SAVIKONTROLEI, ĮVERTINIMO

Valstybinė akreditavimo sveikatos priežiūros veiklai tarnyba prie Sveikatos apsaugos ministerijos (toliau – Akreditavimo tarnyba) gavo ir išnagrinėjo UAB „Optifarma“ 2021-04-22 pateiktą Duomenų apie greituosius antigeno testus, skirtus savikontrolei, pateikimo formą (toliau – Duomenų forma) ir papildomai pateiktus dokumentus, kuriuos įmonė pateikė pagal Profesionaliam naudojimui ir savikontrolei skirtų greitųjų SARS-CoV-2 antigeno testų vertinimo ir naudojimo savikontrolės tikslais tvarkos aprašą, patvirtintą Sveikatos apsaugos ministro 2021 m. balandžio 14 d. įsakymu Nr. V-802 „Dėl Profesionaliam naudojimui ir savikontrolei skirtų greitųjų SARS-CoV-2 antigeno testų vertinimo ir naudojimo savikontrolės tikslais tvarkos aprašo patvirtinimo“ (toliau – Aprašas).

Informuojame, kad vadovaujantis Aprašo 7.2 papunkčiu Akreditavimo tarnyba teikia teigiamą išvadą dėl Duomenų formoje nurodytų Kinijos gamintojo Hangzhou Sejoy Electronics & Instruments Co, Ltd. savikontrolei skirtų greitųjų antigeno SARS-CoV-2 testų (ėminio tipas – nosies landų).

Akreditavimo tarnyba, atsižvelgdama į Aprašo 4 punkte nustatytus reikalavimus, siūlo leisti teikti Lietuvos Respublikos rinkai ir pradėti naudoti šiuos savikontrolei skirtus greituosius antigeno testus:

Gamintojas - Hangzhou Sejoy Electronics & Instruments Co, Ltd., Kinija
Pavadinimas - SARS-CoV-2 antigeno greitasis testas
Mėginio tipas – nosies landų.

Vadovaujantis Aprašo 14[1] Akreditavimo tarnyba savo interneto svetainėje privalo skelbti Profesionaliam naudojimui ir savikontrolei skirtų greitųjų antigeno testų, pritaikytų naudoti savikontrolės tikslais, kuriuos leista teikti Lietuvos Respublikos rinkai ir pradėti naudoti, sąrašą, todėl apie priimtą sprendimą prašome informuoti Akreditavimo tarnybą.

Papildomai teikiame 2021-05-18 Vertinimo pažymos kopiją.

PRIDEDAMA: 2021-05-18 Vertinimo pažymos kopija, 2 lapai.

Direktorė Nora Ribokienė

Originalas paštu nebus siunčiamas

S. Dainiuvienė, tel. (8 5) 247 7669, mob. tel. +37061468912, el. paštas saule.dainiuviene@vaspvt.gov.lt

VERTINIMO PAŽYMA
2021-05-18

Pagal Profesionaliam naudojimui ir savikontrolei skirtų greitųjų SARS-CoV-2 antigeno testų vertinimo ir naudojimo savikontrolės tikslais tvarkos aprašą[1] (toliau – Aprašas)
Lietuvos Respublikos sveikatos sistemos įstatymą (toliau – Įstatymas)
In vitro diagnostikos medicinos priemonių (prietaisų) saugos techninį reglamentą[2] (toliau – IVD MP Reglamentas)

Asmens, pateikusio formą, pavadinimas:	UAB „Optifarma"
Asmens, pateikusio formą, adresas:	Gedvydžių g. 24-2, LT-06308, Vilnius
Registracijos data ir Nr.:	2021-04-22, D1-2712
Trūkstamų / papildomų dokumentų registracijos data ir Nr.:	2021-05-10, D1-3022

1. Duomenys apie greitąjį antigeno testą

1.1.	**Gamintojo pavadinimas**	Hangzhou Sejoy Electronics & Instruments Co, Ltd., Kinija
1.2	**Gamintojo įgaliotasis atstovas**	Shanghai International Holding Corp. GmbH (Europe), Vokietija
1.3.	**Greitojo antigeno testo pavadinimas**	SARS-CoV-2 antigeno greitasis testas
1.4.	**Mėginio tipas**	Nosies landų

2. Pateiktų duomenų ir dokumentų vertinimas:

	Duomenys ir dokumentai	**Įvertinimas: Pateikta (+) Nepateikta (-)**	**Įvertinimas: Atitinka (+) Neatitinka (-)**
2.1.	Ėminio tipas	+	+
Pastabos:			
2.2.	Pakuotės sudėtis	+	+
Pastabos:			
2.3.	Greitojo antigeno testo gamintojo atitikties deklaracijos pagal IVD MP reglamentą kopija	+	+
Pastabos:			
2.4.	Greitojo antigeno testo prekinės pakuotės, pritaikytos neprofesionaliam naudojimui, pavyzdys/ Greitojo antigeno	+	+

[1] Profesionaliam naudojimui ir savikontrolei skirtų greitųjų SARS-CoV-2 antigeno testų vertinimo ir naudojimo savikontrolės tikslais tvarkos aprašas, patvirtintas Sveikatos apsaugos ministro 2021 m. balandžio 14 d. įsakymu Nr. V-802 „Dėl Profesionaliam naudojimui ir savikontrolei skirtų greitųjų SARS-CoV-2 antigeno testų vertinimo ir naudojimo savikontrolės tikslais tvarkos aprašo patvirtinimo"

[2] *In vitro* diagnostikos medicinos priemonių saugos techninio reglamentas, patvirtintas Lietuvos Respublikos sveikatos apsaugos ministro 2001 m. gruodžio 29 d. įsakymu Nr. V-679 „Dėl *In vitro* diagnostikos medicinos priemonių (prietaisų) saugos techninio reglamento patvirtinimo"

	testo prekinės pakuotės, pritaikytos neprofesionaliam naudojimui, išklotinės kopija		
Pastabos:			
2.5.	Lietuvių kalba parengta greitojo antigeno testo naudojimo instrukcija, pritaikyta neprofesionaliam naudotojui	+	+
Pastabos:			
2.6.	Greitojo antigeno testo gamintojo arba gamintojo įgaliotojo atstovo raštiškas patvirtinimas, kad formoje nurodytas profesionaliam naudojimui skirtas greitasis antigeno testas, jo pakuotė, naudojimo instrukcija yra pritaikyti ir tinkami naudoti savikontrolės tikslams	+	+
Pastabos:			
2.7.	Greitojo antigeno testo charakteristikos nustatytiems jautrumo/ specifiškumo reikalavimams (Duomenys pagal išorinę nepriklausomą vertinimo studiją)	+	+
Pastabos:			
2.8.	Dokumentai, patvirtinantys, kad dėl savikontrolei skirtų greitųjų antigeno testų atitikties įvertinimo yra kreiptasi į paskelbtąją įstaigą, kai asmenys siekia teikti savikontrolei skirtus greituosius antigeno testus, kurių atitikimas IVD MP Reglamento reikalavimams dar nėra patvirtintas		
Pastabos: Netaikoma			

Kitos pastabos: Nėra

3. Išvada

Profesionaliam naudojimui skirtų testų reikalavimai, nurodyti Aprašo 4 punkte	**Įvertinimas: Atitinka (+) Neatitinka (-)**
Profesionaliam naudojimui skirtas greitojo antigeno testas atitinka IVD MP reglamento reikalavimus, o dėl savikontrolei skirtų antigenų testų atitikties IVD MP reikalavimams yra kreiptasi į paskelbtąją įstaigą	+
Profesionaliam naudojimui skirto greitojo antigeno testo jautrumas ne mažesnis nei 80 proc. lyginant su SARS-CoV-2 (2019-nCoV) RNR nustatymo tikralaikės PGR metodu tyrimais eminiams, kurių ciklo slenkstis (angl. *cycle threshold*) yra pasiskirstęs intervale 32 (įskaitytinai), specifiškumas – ne mažesnis nei 97 proc.	+
Profesionaliam naudojimui skirtas greitojo antigeno testas pritaikytas naudoti nosies landų ir (ar) seilių eminių tyrimams	+
Profesionaliam naudojimui skirtas greitojo antigeno testas turi neprofesionaliam naudotojui pritaikytą išorinę pakuotę ir naudojimo instrukciją	+

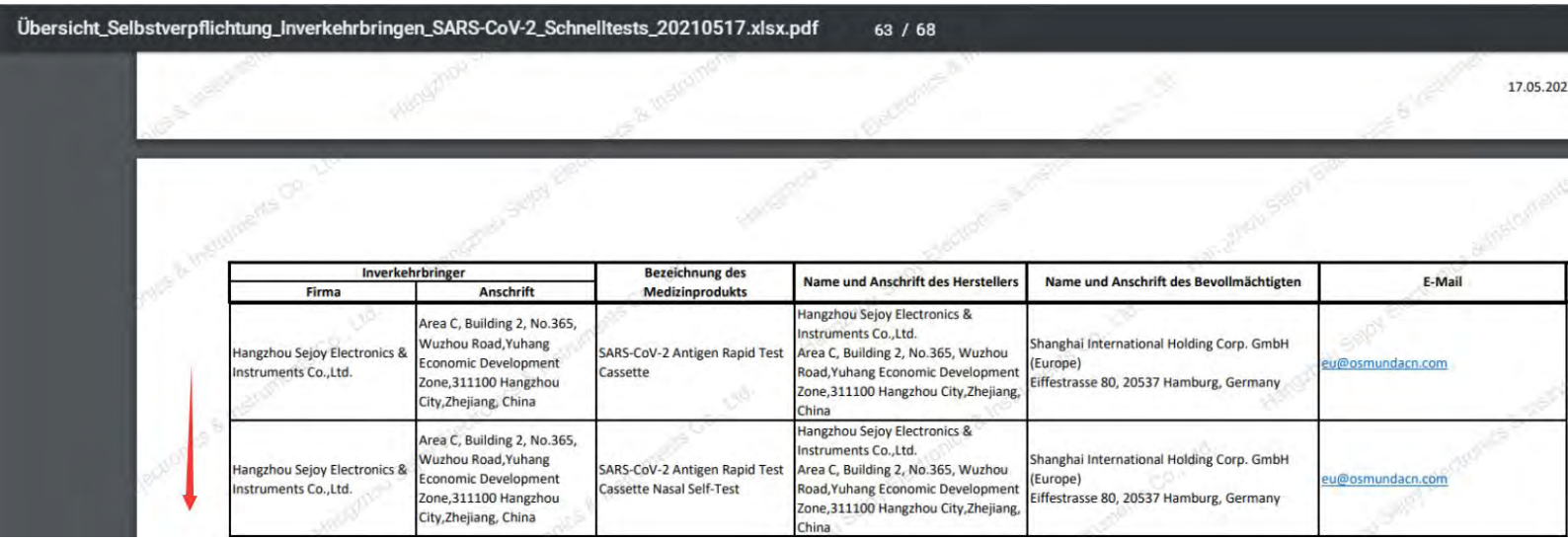
Dokumentus vertino:
Medicinos prietaisų rinkos priežiūros skyriaus
vyr. specialistė Saulė Dainuvienė

Medicinos prietaisų rinkos priežiūros skyriaus
vedėja Jolanta Karavackaitė

REGISTRATION CERTIFICATE OF AUSTRIA

(For SARS-CoV-2 Antigen Rapid Test Cassette

& SARS-CoV-2 Antigen Rapid Test Cassette Nasal Self-Test)



Inverkehrbringer		Bezeichnung des Medizinprodukts	Name und Anschrift des Herstellers	Name und Anschrift des Bevollmächtigten	E-Mail
Firma	Anschrift				
Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China	SARS-CoV-2 Antigen Rapid Test Cassette	Hangzhou Sejoy Electronics & Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany	eu@osmundacn.com
Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China	SARS-CoV-2 Antigen Rapid Test Cassette Nasal Self-Test	Hangzhou Sejoy Electronics & Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany	eu@osmundacn.com

Inverkehrbringer		Bezeichnung des Medizinprodukts	Name und Anschrift des Herstellers	Name und Anschrift des Bevollmächtigten
Firma	Anschrift			
Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China	SARS-CoV-2 Antigen Rapid Test Cassette	Hangzhou Sejoy Electronics & Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China	SARS-CoV-2 Antigen Rapid Test Cassette Nasal Self-Test	Hangzhou Sejoy Electronics & Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

REGISTRATION CERTIFICATE OF FRANCE

(SARS-CoV-2 Antigen Rapid Test Cassette Self-Test Use)

SARS-CoV-2 antigenic self-test

General informations

Type of test
Antigenic

Targets
NOT

Test subtype
Self test

Manufacturer's name
Hangzhou Sejoy Electronics &. Instruments co.,

CE marking
No

HAS compliance
Yes

Technical informations

Number of targets
1

Type of sample required for the test (one type per test)
Nasal

LAST NAME	MAKER	DISTRIBUTER	THIS	EU	CNR	TEST SUBTYPE	TARGETS	TYPE OF SAMPLE
SARS-CoV-2 antigenic self-test	Hangzhou Sejoy Electronics &. Instruments co.,					Self test	NOT	Nasal
SARS-CoV-2 Antigen Rapid Test Cassette	Hangzhou Sejoy Electronics & Instruments Co., Ltd.					Non-automated antigen (including TROD)	NOT	Nasopharyngeal

Nombre de tests

2/481

Dans le cadre de la stratégie nationale du schéma vaccinal complet à une dose chez les personnes immunocompétentes sans antécédent connu d'infection au SARS-CoV2, **les TROD sérologiques utilisés doivent détecter a minima les cibles suivantes : IgG antiprotéine S ou IgG antiprotéine N+S**.

Cliquez pour accéder à la liste commune européenne TAG

Signalement

JE SIGNALE

Contextes juridiques

Cliquez pour déplier et télécharger les fichiers des contextes juridiques

Statut: ☐ CE ☐ CNR ☐ UE ☐ HAS

Type de test: ----

Sous-type de test: ----

Cibles: –

Type prélèvement: ----

Rechercher: sejoy

Tableau de bord des tests

Cliquez pour déplier et visualiser les graphes du tableau de bord

2 tests affichés

Options

NOM	FABRICANT	DISTRIBUTEUR	CE	UE	CNR	SOUS-TYPE DE TEST	CIBLES	TYPE DE PRÉLÈVEMENT
Autotest antigénique SARS-CoV-2	Hangzhou Sejoy Electronics &.Instruments co.,		✓	✓	✓	Autotest	N	Nasal
SARS-CoV-2 Antigen Rapid Test Cassette	Hangzhou Sejoy Electronics& Instruments Co.,Ltd.		✓	✓	✓	Antigénique non automatisé (dont TROD)	N	Nasopharyngé

REGISTRATION CERTIFICATE OF MALAYSIA

39	Medical Innovation Ventures Sdn.Bhd	Sejoy SARS-CoV-2 Antigen Rapid Test Cassette	Hangzhou Sejoy Electronics & Instruments Co. Ltd., P.R. China	COVG-602ST	RTK-Antigen (Self-test)	Saliva

REGISTRATION CERTIFICATE OF THAILAND

แบบ ป.ท.

ใบรับรองการประเมินเทคโนโลยีเครื่องมือแพทย์

ใบรับรองการประเมิน ที่ T 6400466

ใบรับรองการประเมินฉบับนี้ให้ไว้แก่

บริษัท เฮลธ์ อิมแพค จำกัด

ผู้จดทะเบียนสถานประกอบการผลิตหรือนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ สน. 274/2553

เพื่อแสดงว่าเป็นผู้ผลิตหรือนำเข้าเครื่องมือแพทย์ที่ได้รับการประเมินเทคโนโลยี ตามมาตรา ๖ (๘)

แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ สำหรับเครื่องมือแพทย์

SARS-CoV-2 Antigen Rapid Test Cassette ชื่อทางการค้า HEALTH IMPACT

รายละเอียดเครื่องมือแพทย์ รหัสสินค้า COVG-602

ขนาดบรรจุ 1 ชุดการทดสอบต่อกล่อง

ประเภทเพื่อการวินิจฉัยภายนอกร่างกาย ชนิดเพื่อการวินิจฉัยรายบุคคล แบบตรวจคัดกรอง

แบบตรวจหา แอนติเจนด้วยตนเอง (Home use/Self-test)

สิ่งส่งตรวจ Nasal swab

ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ในต่างประเทศ

Hangzhou Sejoy Electronics & Instruments Co., Ltd. Area C, Building 2, No.365, Wuzhou Road,

Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

ณ สถานที่ผลิตหรือนำเข้าเครื่องมือแพทย์ชื่อ บริษัท เฮลธ์ อิมแพค จำกัด

ตั้งอยู่เลขที่ 31/5

ตรอก/ซอย อรุณอมรินทร์ 39 ถนน อรุณอมรินทร์ หมู่ที่ -

ตำบล/แขวง อรุณอมรินทร์ อำเภอ/เขต บางกอกน้อย

จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10700 โทรศัพท์ 0 2433 9944 โทรสาร

ออกให้ไว้ ณ วันที่ 10 เดือน พฤศจิกายน พ.ศ. 2564

([illegible])

[illegible] ผู้อนุญาต

[illegible]

CERTIFICATE

EC Certificate No. 1434-IVDD-474/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Hangzhou Sejoy Electronics & Instruments Co., Ltd
Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test Cassette
COVG-602ST

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 22.10.2021 to 27.05.2024

The date of issue of the Certificate: 22.10.2021

The date of the first issue of the Certificate: 22.10.2021

CE 1434

Issued under the Contract No. MD-100/2021
Application No: 192/2021
Certificate bears the qualified signature.
Warsaw, 22/10/2021
Module A1
FBM-30-E_10

Anna Malgorzata Wyroba

Vice-President

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ANTIGEN TESTING

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- Easy To Carry
- High Sensitivity And Specificity
- Fast Results At 10 Minutes
- Able To Detect Early Infection

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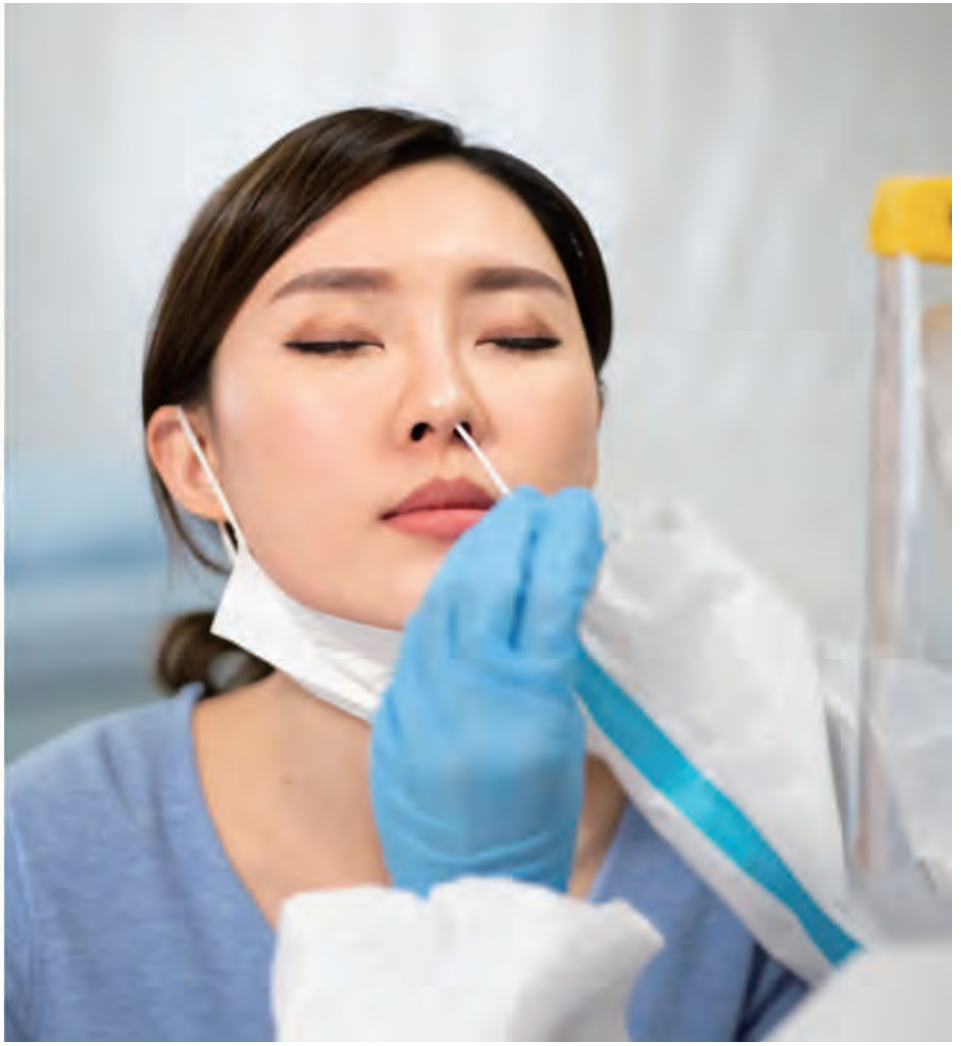
1. Germany — Federal Institute for Drugs and Medical Devices
2. France — MINISTÈRE DE L'EUROPE ET DES AFFAIRES ÉTRANGÈRES
3. Belgium — fagg
4. Austria — Austrian Federal Office for Safety in Health Care BASG
5. Czech Republic — MINISTERSTVO ZDRAVOTNICTVÍ Palackého náměstí 375/4, 128 01 Praha 2
6. Slovakia — PUBLIC HEALTH AUTHORITY OF THE SLOVAK REPUBLIC
7. Slovenia — REPUBLIC OF SLOVENIA GOV.SI
8. Bulgaria — Ministry of Health
9. Malaysia — Medical Device Authority Malaysia
10. Chile — Ministerio de Salud
11. Ecuador — U.S. Embassy & Consulate in Ecuador
12. Lithuania — VALSTYBINĖ AKREDITAVIMO SVEIKATOS PRIEŽIŪROS VEIKLAI TARNYBA PRIE SVEIKATOS APSAUGOS MINISTERIJOS
13. Thailand — ใบรับรองการประเมินเทคโนโลยีเครื่องมือแพทย์
14. Poland — gov.pl



www.sejoy.com
Info@sejoy.com
Area C, Building 2, No.365, Wuzhou Road,
Yuhang Economic Development Zone,311 100 Hangzhou City,Zhejiang, China

Self Testing In

1. CE1434 — CERTIFICATE
2. Germany — Federal Institute for Drugs and Medical Devices (In Progress)
3. France — MINISTÈRE DE L'EUROPE ET DES AFFAIRES ÉTRANGÈRES
4. Czech Republic — MINISTERSTVO ZDRAVOTNICTVÍ, Palackého náměstí 375/4, 12801 Praha 2
5. Austria — Austrian Federal Office for Safety in Health Care BASG
6. Lithuania — VALSTYBINĖ AKREDITAVIMO SVEIKATOS PRIEŽIŪROS VEIKLAI TARNYBA PRIE SVEIKATOS APSAUGOS MINISTERIJOS
7. Malaysia — Medical Device
8. Thailand
9. Bulgaria — Ministry of Health

Area C, Building 2, No.365, Wuzhou Road,
Yuhang Economic Development Zone,311 100 Hangzhou City,Zhejiang, China
Info@sejoy.com
www.sejoy.com

Validated In

Germany

The test has been evaluated and approved by a reputable laboratory from Germany:

Clinical Study Results (>100 positive samples; > 100 negative samples):

1. Analytical Results with correlation to Ct-values of the positive samples:

Ct-value	No. of Samples	No. of true positive Rapid Test Samples	Sensitivity of SARS-CoV-2 Antigen Rapid Test
≤30	82	82	100%
≤32	94	92	97.9%
≤34	102	98	96.1%
≤36	109	103	94.5%

2. Analytical Results with correlation to Ct-values of the negative samples:

No. of Samples	No. of true negative Rapid Test Samples	Sensitivity of SARS-CoV-2 Antigen Rapid Test
82	82	100%

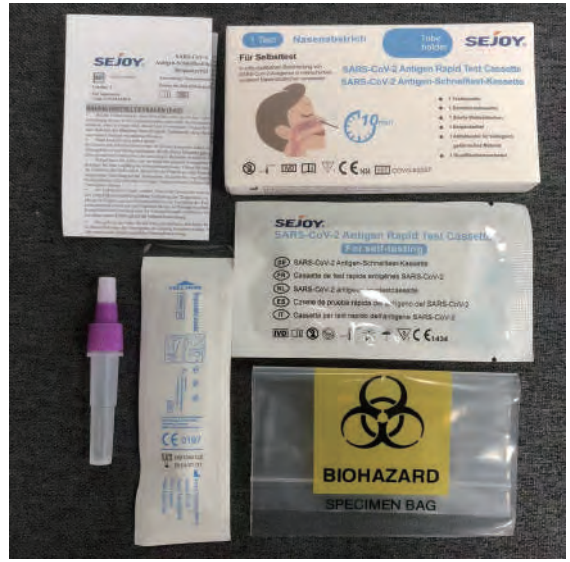
1. **France**:
SPIRAL Evaluation with good results: Sensitivity 97.1%, Specifificity 100%

2. **Malaysia**:
IMR(Institute for Medical Research) Evaluation with good results: Sensitivity 96.0%, Specifificity 100%

3. **Thailand**:
Evaluation with good results: Sensitivity 100%, Specifificity 100%

www.sejoy.com Info@sejoy.com Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone,311 100 Hangzhou City,Zhejiang, China

Product pictures



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